DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

EOS Imaging
% Mr. John J. Smith
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street NW
WASHINGTON DC 20004

Re: K141137
Trade/Device Name: sterEOS Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 18, 2014
Received: August 18, 2014

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K141137

Device Name
sterEOS workstation

Indications for Use *(Describe)*

The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general device for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system including interactive 2D measurement tools.

When using 2D X-ray images obtained with the EOS Imaging EOS System, the sterEOS Workstation provides interactive 3D measurement tools:

- To aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients. The 3D measurement tools include interactive analysis based either on identification of anatomical landmarks for postural assessment or on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data for spine modeling. The model of bone structures is not intended for use to assess individual vertebral abnormalities and is indicated only for patients 7 years and older. For postural assessment, a set of comparative tools is provided allowing the comparison of performed measurements to reference values for patients over 18 years old.
- To aid in the analysis of lower limbs alignment and related disorders and deformities based on angle and length measurements. The 3D measurement tools include interactive analysis based either on identification of lower limb alignment landmarks or as for the spine, on a model of bone structures derived from an a priori image data set. The model of bone structures is not intended for use to assess individual bone abnormalities. The 3D package including model-based measurements and torsion angles is indicated only for patients 15 years or older. Only the 2D/3D ruler is indicated for measurements in patients younger than 15 years old.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) SUMMARY

EOS imaging's sterEOS Workstation

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

EOS imaging
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FRANCE

Phone: + 33 1 55 25 60 60
Facsimile: + 33 1 55 25 60 61

Contact Person: Karine Chevrie, Quality and Regulatory Affairs Officer

Date Prepared: August 15, 2014

Trade Name: sterEOS Workstation

Common or Usual Name: sterEOS Workstation

Classification: 21 C.F.R. § 892.2050; image processing radiological system

Product Code: LLZ

Predicate Devices: EOS imaging's sterEOS Workstation (K130395)

Purpose of the Traditional 510(k) notice:

The sterEOS workstation is a modification to the cleared sterEOS.

Device Description

The sterEOS Workstation is a general system for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system, including interactive 2D measurement tools.

When used with 2D X-ray images obtained with the EOS imaging's EOS System (K123740), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of skeletal deformities in spine and lower limbs.

Indications for Use

The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general device for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system including interactive 2D measurement tools.

When using 2D X-ray images obtained with the EOS Imaging EOS System, the sterEOS Workstation provides interactive 3D measurement tools:

- To aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients. The 3D measurement tools include interactive analysis based either on identification of anatomical landmarks for postural assessment or on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data for spine modeling. The model of bone structures is not intended for use to assess individual vertebral abnormalities and is indicated only for patients 7 years and older. For postural assessment, a set of comparative tools is provided allowing the comparison of performed measurements to reference values for patients over 18 years old.

- To aid in the analysis of lower limbs alignment and related disorders and deformities based on angle and length measurements. The 3D measurement tools include interactive analysis based either on identification of lower limb alignment landmarks or as for the spine, on a model of bone structures derived from an a priori image data set. The model of bone structures is not intended for use to assess individual bone abnormalities. The 3D package including model-based measurements and torsion angles is indicated only for patients 15 years or older. Only the 2D/3D ruler is indicated for measurements in patients younger than 15 years old.

Technological Characteristics

The technological characteristics of the modified sterEOS Workstation are essentially identical to the cleared sterEOS Workstation (K130395). Like the cleared sterEOS Workstation, the instant device is based on the Windows 7 operating system, runs on off-the-shelf hardware, supports DICOM 3.0 formatted images and its user interface follows typical clinical workflow patterns to process, review, and analyze digital images. The main differences with the cleared sterEOS Workstation consist of the following minor software modifications:

- Introduction of a new workflow dedicated to global postural assessment.
- Improvement of the lower limb 3D modeling using automatic adjustment.
- Addition of an export feature to allow for the transfer of sets of data for third-party applications.

Performance Data

Software modifications have been verified at the unit level. After integration, system software V&V testing was performed to ensure compliance with specifications, performance and non-regression. Additional performance and functional testing has confirmed the equivalent performance of the modified sterEOS compared to the predicate sterEOS workstation.

Substantial Equivalence

The device has similar intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the device is as safe and effective as the company's cleared sterEOS device and, thus, is substantially equivalent.